

Attorney Docket No.: INT-0004
Inventors: Mattern et al.
Serial No.: 10/002,653
Filing Date: October 19, 2001
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This listing of the claims will replace all prior versions and listings of claims in the application:

Listing of the claims:

Claim 1: (previously canceled)

Claim 2: (previously amended) The scaffold or matrix of claim 13 further comprising a silicone layer applied to the collagen and glycosaminoglycan co-precipitate prior to cross-linking.

Claim 3: (previously amended) A terminally sterilized matrix or scaffold comprising the scaffold or matrix of claim 13 terminally sterilized by electron beam irradiation.

Claim 4: (previously amended) A terminally sterilized matrix or scaffold comprising the scaffold or matrix of claim 2 terminally sterilized by electron beam irradiation.

Claim 5: (currently amended) A method for producing the scaffold or matrix of claim 13 comprising:

(a) adding glycosaminoglycan to a collagen solution to co-precipitate collagen fibrils coated with glycosaminoglycan from

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the solution; and

(b) cross-linking the collagen and glycosaminoglycan co-precipitate with glutaraldehyde at a density of cross-linkage and under conditions which ~~stabilizes~~ stabilize the scaffold or matrix toward electron beam radiation at about 15 to about 80 kGy so that the matrix or scaffold retains characteristics to function as a structural support for cell and tissue ingrowth.

Claim 6: (previously amended) The method of claim 5 wherein cross-linking of the collagen and glycosaminoglycan co-precipitate is performed with glutaraldehyde at a concentration greater than 0.25%.

Claim 7: (previously amended) The method of claim 5 wherein the collagen and glycosaminoglycan co-precipitate is subjected to two or more glutaraldehyde cross-linking steps.

Claim 8: (original) The method of claim 7 wherein the two or more cross-linking steps are performed with glutaraldehyde at 0.25%.

Claim 9: (previously amended) A method for producing a terminally sterilized matrix or scaffold comprising:

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(a) producing a scaffold or matrix of claim 13;
(b) sealing the composition in a package; and
(c) exposing the composition in the sealed package to
electron beam radiation.

Claim 10: (canceled)

Claim 11: (original) A terminally sterilized matrix or scaffold
produced in accordance with the method of claim 9.

Claim 12: (original) A method for regenerating dermal or sub-
dermal tissue in a subject comprising applying to or implanting
within the subject the terminally sterilized matrix or scaffold
of claim 3 at or near an excision site of dermal or subdermal
tissue or a site where augmentation of dermal or subdermal tissue
is required.

Claim 13: (currently amended) A scaffold or matrix comprising a
collagen and glycosaminoglycan co-precipitate cross-linked with
glutaraldehyde at a density of cross-linkage and under conditions
which ~~stabilizes~~ stabilize the scaffold or matrix toward electron
beam radiation at about 15 to about 80 kGy so that the matrix or

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scaffold retains characteristics to function as a structural support for cell and tissue ingrowth.

Claim 14: (new) The scaffold of claim 13 wherein the conditions of cross-linkage comprise glutaraldehyde in an acetic acid solution.

Claim 15: (new) The method of claim 5 wherein the conditions of cross-linkage comprise glutaraldehyde in an acetic acid solution.

Claim 16: (new) The method of claim 6 wherein the glutaraldehyde concentration is 0.5%.